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510(k) SUMMARY

This 510(k) Summary is submitted in accordance with 21 CFR Part 807, Section 807.92.

Submitter's Name:	Veryan Medical Limited
Submitter's Address:	Sir Leon Bagrit Centre Mechanical Engineering Building Imperial College Exhibition Road London, SW7 2AZ
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Contact Person:	Gill Cash

Date Prepared:	May 18, 2005
Device Trade Name:	SwirlGraft™ Bypass Graft SwirlGraft™ Vascular Access Graft
Device Common Name:	Vascular Graft
Device Classification Name:	Vascular Graft Prosthesis of 6mm and Greater Diameter
Device Classification:	Class II

Intended Use:

The SwirlGraft™ Bypass Graft is intended for bypass or reconstruction of occluded or diseased peripheral arterial blood vessels.

The SwirlGraft™ Vascular Access Graft is intended for use as a subcutaneous arterio-venous conduit for vascular access.

Summary of Substantial Equivalence:

The SwirlGraft™ Bypass and Vascular Access Grafts are substantially equivalent to Sulzer Medica's Sulzer Vascutek ePTFE Vascular Prosthesis (K992832).

Device Description:

The SwirlGraft™ Bypass and Vascular Access Grafts are 6 mm diameter expanded polytetraflouro-ethylene (ePTFE) vascular grafts that are manufactured with a small amplitude helical geometry along their length. The SwirlGraft™ Bypass Graft has a thin wall ePTFE construction and a full ePTFE external support. The SwirlGraft™ Vascular Access Graft is a standard wall ePTFE construction with no external support.

Technological Characteristics:

Comparative testing of the SwirlGraft™ Bypass and Vascular Access Grafts with the predicate device found that the technological characteristics, performance and principle of operation were substantially equivalent.

Performance Data:

Bench testing and animal data demonstrated that the safety and effectiveness of the SwirlGraft™ Bypass and Vascular Access Grafts is equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Veryan Medical, Ltd.
c/o Ms. Judith Danielson
Senior Regulatory consultant
CardioMed Device Consultants, LLC
1327 Bluegrass Way
Gambrills, MD 21054

Re: K051312
Trade Name: Vascular Solutions SwirlGraft™
Regulation Number: 21 CFR 870.3460
Regulation Name: Vascular Graft
Regulatory Class: II (two)
Product Code: DSY
Dated: October 04, 2005
Received: October 05, 2005

Dear Ms. Danielson;

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0295. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Donna R. Bachman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K051312

Device Name: SwirlGraft™ Bypass Graft
SwirlGraft™ Vascular Access Graft

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Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Vachuska

(Division Sign-Off)
Division of Cardiovascular Devices

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